IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBOR PHARMACEUTICALS, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Arbor Pharmaceuticals, LLC ("Arbor" or "Plaintiff"), for its Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva" or "Defendants"), hereby alleges as follows:

The Parties

1. Arbor is a limited liability company organized and existing under the laws of the state of Delaware, having a principal place of business at 6 Concourse Parkway, Suite 1800, Atlanta, GA 30328.

2. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Upon information and belief, Teva USA is a wholly owned subsidiary of Teva Ltd.

3. Upon information and belief, Teva Ltd. is a corporation organized and existing under the laws of the State of Israel, having a principal place of business at 5 Basel Street, Petah Tikva, 49131, Israel.

Nature of the Action

4. This is a civil action for infringement of United States Patent Nos. 8,791,153 ("the '153 patent") and 8,927,595 ("the '595 patent") (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq*.

Jurisdiction & Venue

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Upon information and belief, Teva USA is a Delaware corporation and has a registered agent in the State of Delaware located at Corporate Creations Network Inc., 3411 Silverside Road, Tatnall Building Suite 104, Wilmington, Delaware 19810.

7. This Court has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the facts that, *inter alia*, Teva USA is a Delaware corporation and thus resides in Delaware, and Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Arbor, including in the State of Delaware. Defendants have indicated that they intend to engage in the commercial manufacture, use, or sale of Ivermectin Lotion, 0.5% ("the ANDA Product") under Abbreviated New Drug Application No. 212485 ("the '485 ANDA") before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

8. Upon information and belief, Teva Ltd. is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Teva USA.

9. Upon information and belief, Teva USA is in the business of, *inter alia*, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates.

10. Upon information and belief, Teva Ltd. and/or Teva USA hold Pharmacy Wholesale Licenses from the State of Delaware, under License Nos. A4-0001447, A4-0001468, and A4-0002545, and Distributor/Manufacturer Licenses for Controlled Substances from the State of Delaware, under License Nos. DM-0007115 and DM-0006546.

11. Upon information and belief, Teva Ltd. and Teva USA have participated and collaborated in the preparation, filing, and seeking FDA approval of the '485 ANDA for the ANDA Product; continue to participate and collaborate in seeking FDA approval of the '485 ANDA; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the ANDA Product throughout the United States including the State of Delaware.

12. Defendants' infringing activities with respect to the filing of the '485 ANDA and intent to commercialize the ANDA Product have led and/or will lead to foreseeable harm and injury to Arbor.

13. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, by virtue of the fact that, upon information and belief, *inter alia*, Defendants have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

14. This Court also has personal jurisdiction over Defendants, and venue is proper in this district, because they have previously submitted to the jurisdiction of this Court and have

further previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Teva Pharms. USA, Inc. v. Mylan Pharms. Inc.*, C.A. No. 17-249-GMS (D. Del.) (Teva USA and Teva Ltd. filed complaint for patent infringement); *Teva Pharms. USA, Inc. v. Doctor Reddy's Labs., Ltd.*, C.A. No. 16-1267-CFC (D. Del.) (same); *Teva Pharms. USA, Inc. v. Biocon Ltd.*, C.A. No. 16-278-CFC (D. Del.) (same); *Teva Pharms. USA, Inc. v. Dr. Reddy's Labs., Ltd.*, C.A. No. 15-306-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Amneal Pharms. LLC.*, C.A. No. 15-124-GMS (D. Del.) (same); *Teva Pharms. USA, Inc. v. Synthon Pharms., Inc.*, C.A. No. 14-1419-GMS (D. Del.) (same); *Insys Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 17-1303-CFC (D. Del.) (Teva USA and Teva Ltd. did not contest jurisdiction, and Teva USA filed a counterclaim); *Orexo AB v. Actavis Elizabeth LLC*, C.A. No. 17-758-CFC (D. Del.) (Teva USA and Teva Ltd. did not contest jurisdiction); *Momenta Pharms., Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 17-109-CFC (D. Del.) (same); *Amneal Pharms. LLC v. Teva Pharms. USA, Inc.*, C.A. No. 17-074-GMS (D. Del.) (same); *Onyx Therapeutics, Inc. v. Teva Pharms. USA, Inc.*, C.A. No. 17-449-LPS (Teva USA filed counterclaims and did not contest jurisdiction); *Bayer HealthCare, LLC v. Teva Pharms. USA, Inc.*, C.A. No. 16-1220-LPS (D. Del.) (same).

15. Alternatively, should the Court find that the above facts do not establish personal jurisdiction over Teva Ltd. in this action, this Court may exercise jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Teva Ltd. has sufficient contacts with the United States as a whole, including but not limited to submitting various ANDAs to the FDA, and manufacturing and selling active pharmaceutical

ingredients that are used in pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

Arbor's NDA and the Patents-In-Suit

17. Arbor holds New Drug Application ("NDA") No. 202736 for SKLICE® (ivermectin lotion), and is the exclusive distributor of SKLICE® in the United States.

18. On July 29, 2014, the '153 patent, entitled "Topical avermectin formulations and methods for elimination and prophylaxis of susceptible and treatment-resistant strains of head lice" was duly and legally issued. A copy of the '153 patent is attached as Exhibit A.

19. Arbor owns the '153 patent.

20. On January 6, 2015, the '595 patent, entitled "Topical avermectin formulations and methods for elimination and prophylaxis of susceptible and treatment resistant strains of head lice" was duly and legally issued. A copy of the '595 patent is attached as Exhibit B.

21. Arbor owns the '595 patent.

22. The patents-in-suit are listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for SKLICE®.

Teva's ANDA and Paragraph IV Notification

23. Upon information and belief, Teva USA, with the collaboration or assistance of Teva Ltd., submitted the '485 ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or

importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

24. Arbor received written notification of Teva's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Paragraph IV Notification") dated November 28, 2018.

25. This action is being commenced by Arbor within 45 days of the date of its receipt of the Paragraph IV Notification.

26. The Paragraph IV Notification was accompanied by an Offer of Confidential Access ("OCA") to certain confidential information regarding the ANDA Product. Arbor and Teva subsequently exchanged markups of the OCA in an attempt to reach agreement on the terms for confidential access. As of the filing of this Complaint, however, the parties have not been able to reach an agreement.

27. To date, Teva has not provided Arbor with a copy of any portions of the '485 ANDA or any information regarding the ANDA Product, beyond the information set forth in the Paragraph IV Notification.

28. The limited information relating to the ANDA Product that was provided in Teva's Paragraph IV Notification does not demonstrate that the ANDA Product, which Teva is asking the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the patents-in-suit.

Teva's Infringement of the Patents-In-Suit

29. Plaintiff re-allege paragraphs 1–28 as if fully set forth herein.

30. By seeking FDA approval of the '485 ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United

States, of the ANDA Product prior to the expiration of the patents-in-suit, Defendants have infringed those patents under 35 U.S.C. § 271(e)(2)(A).

31. Upon information and belief, the '485 ANDA contains a certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the patents-in-suit are not infringed and invalid. Teva notified Arbor of that certification and provided a statement of the alleged bases for it its claims.

32. Defendants are jointly and severally liable for infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A). Upon information and belief, Defendants actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of the '485 ANDA seeking to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of the ANDA Product prior to the expiration of the patents-in-suit.

33. Moreover, if Defendants manufacture, use, offer for sale, or import into the United States any of the ANDA Product, or induce or contribute to any such conduct, prior to the expiration of the patents-in-suit, including any applicable exclusivities or extensions, they would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b) and/or (c).

34. Arbor is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the '485 ANDA be a date that is not earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Arbor becomes entitled.

35. Arbor will be irreparably harmed by Teva's infringing activities unless those activities are enjoined by this Court. Arbor does not have an adequate remedy at law.

Prayer for Relief

Plaintiff requests that the Court grant the following relief:

A. An order that Defendants have infringed the patents-in-suit by submitting the '485 ANDA to the FDA;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the '485 ANDA will not be earlier than the expiration date of the patents-in-suit, or any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiff is or becomes entitled;

C. An order permanently enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from manufacturing, using, offering to sell, selling, marketing, distributing, or importing the ANDA Product identified in this Complaint, or any product that infringes the patents-in-suit, prior to the expiration of the patents-in-suit, including any extensions to which Plaintiff is or becomes entitled;

D. That Plaintiff be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the patents-in-suit, within the United States prior to the expiration of the patents-in-suit, including any later expiration of any patent term extension or exclusivity for the patents-in-suit to which Plaintiff is or will become entitled, and that any such monetary relief be awarded to Plaintiff with prejudgment interest;

E. That this case be declared exceptional and Plaintiff be awarded its attorneys' fees; and

F. Such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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